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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/826,337	04/19/2004	Jorg Senn-Bilfinger	25079Y	9566
34375	7590	06/22/2006	EXAMINER	
NATH & ASSOCIATES PLLC 112 South West Street Alexandria, VA 22314			RAHMANI, NILOOFAR	
			ART UNIT	PAPER NUMBER
			1625	

DATE MAILED: 06/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/826,337

Applicant(s)

SENN-BILFINGER ET AL.

Examiner

Niloofer Rahmani

Art Unit

1625

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 19 April 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 15-30 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 15-30 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

### **DETAILED ACTION**

1. The office action of 12/07/2005 has been vacated. Claims 15-30 are currently pending in the instant application. Claims 1-14 are cancelled.

#### ***Priority***

2. This application is a CON of 10/182,619, filed on 10/01/2002 (ABN), which is a 371 of PCT/EP01/03514, filed on 03/28/2001, which claims the priority of EP 00106695, filed on 03/29/2000.

3. The rejection of claims 15-30 over US 6,160,119 or US 6,197,783 or WO 00/26217 in view of Bundgaard DE 4308095 under 35 U.S.C. 103(a) is withdrawn for reason of applicants argument in paper dated 04/13/2006.

4. The rejection of claims 25-26 for " pharmaceutical composition " under 35 U.S.C. 112, second paragraph is maintained for reason of record. Applicants argue that the newly submitted claims recite " therapeutically effective amount". It is the examiner's position that the instant claims do not recite "therapeutically effective amount". Pharmaceutical compositions by definition must be effective yet non-toxic. It is recommended that "therapeutically effective amount" be incorporated in the claims.

5. The rejection of claims 15-30 for "hydrate" under 35 U.S.C. 112, first paragraph is maintained for reason of record. Applicants argue that the specification clearly contains written description for the term "hydrate" at page 7, 2<sup>nd</sup> paragraph. It is the examiner's position that the instant claims do not have

clearly support in the specification. Hydrate is unpredictable because there are different hydrates. There are  $\frac{1}{2}$  hydrate, 3 hydrate, or  $\frac{3}{4}$  hydrate, etc.

6. The rejection of claims 15-30 over Grundler et al. WO 98/54188 or Simon et al., WO 98/42707 in view of Bundgaard DE 4308095 under 35 U.S.C. 103(a) is maintained for reason of record. Applicants argue that first, the prior art relied upon, coupled with the knowledge generally available in the art at the time of the invention, must contain some suggestion or incentive that would have motivated the skilled artisan to modify a reference. Lastly, the prior art references must teach or suggest all the limitations of the claims. It is the examiner's position that the instant claims are the prodrug formulation of hydroxyl.

7. The rejection of claims 15-30 over the claims 1-8 Senn-Bilfinger et al. US 6,916,825 or the claims 1-11 Senn-Bilfinger et al. US 6,384,048 or the claims 1-10 Senn-Bilfinger et al. US 6,160,119 or the claims 1-14 Senn-Bilfinger et al. US 6,197,783 or the claims 1-13 Senn-Bilfinger et al. US 6,436,953 or the claims 1-8 Senn-Bilfinger et al. US 6,696,461(ap# 10/182,654) or the claims 1-15 Senn-Bilfinger et al. US 6,696,460 (ap# 10/103733) in view of Bundgaard DE 4308095 under Obvious Double Patenting is maintained for reason of record. Applicants argue that the newly presented claims have different scope than previous claims 1-14 and are not an obvious variation of the claims. It is the examiner's position that the instant claims wherein  $R_{5a}$  being radical  $-OR'$  which is  $R'$  is  $-CH_2-OR_8$  is corresponded to the  $R_{5a}$  being 1-4C-alkoxy-1-4C-alkoxy in the prior art.

Bundgaard et al. DE 4308095 teaches that prodrugs can change under physiological condition to drugs.

8. The rejection of claims 15-26 over the claims 1-6 Senn-Bilfinger et al. ap # 10/485,514 in view of Bundgaard DE 4308095 under Obvious Double Patenting is maintained for reason of record. Applicants argue that the newly presented claims have different scope than previous claims 1-14 and are not an obvious variation of the claims. It is the examiner's position that the instant claims wherein R<sub>5a</sub> being radical -OR' which is R' is -CH<sub>2</sub>-OR<sub>8</sub> is corresponded to the R<sub>5a</sub> being 1-4C-alkoxy-1-4C-alkoxy in the prior art. Bundgaard et al. DE 4308095 teaches that prodrugs can change under physiological condition to drugs.

**9. Claim Rejections - 35 USC § 112**

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 27-30 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter, which was not describe in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

The specification lacks description of the claim i.e. "gastrointestinal illness". In the specification, there is no description of gastrointestinal illness, which is broader term than gastrointestinal disease. On page 43 of the specification,

applicants described gastrointestinal disease not gastrointestinal illness.  
Therefore, the specification lacks description for the term “gastrointestinal illness”.

**10. *Claim Rejections - 35 USC § 112***

Claims 27-30 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. Material added by amendment, which does not have clear support in the specification, claims as originally filed. Thus, the term “illness” is NEW MATTER.

**11. *Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S.

patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claim 15 is rejected under 35 U.S.C. 102(e) as being anticipated by Senn-Bilfinger et al., US 6,160,119. Senn-Bilfinger et al. disclosed the instant claimed compound on column 1, lines 54-57, wherein R<sub>5a</sub> being 1-4C-alkoxy-1-4C-alkoxy which is corresponded to R<sub>5a</sub> being radical –OR' wherein R' is –CH<sub>2</sub>-OR<sub>8</sub> in the instant claim. Therefore, the instant claim is anticipated by Senn-Bilfinger et al.

**12.** Claim 15 is rejected under 35 U.S.C. 102(e) as being anticipated by Senn-Bilfinger et al., US 6,197,783. Senn-Bilfinger et al. disclosed the instant claimed compound on column 1, lines 52-54, wherein R<sub>5a</sub> being 1-4C-alkoxy-1-4C-alkoxy which is corresponded to R<sub>5a</sub> being radical –OR' wherein R' is –CH<sub>2</sub>-OR<sub>8</sub> in the instant claim. Therefore, the instant claim is anticipated by Senn-Bilfinger et al.

**13.** Claim 15 is rejected under 35 U.S.C. 102(b) as being anticipated by Senn-Bilfinger et al., WO 98/54188. Senn-Bilfinger et al. disclosed the instant claimed compound on page 2, lines 3-5, wherein R<sub>5a</sub> being 1-4C-alkoxy-1-4C-alkoxy which is corresponded to R<sub>5a</sub> being radical –OR' wherein R' is –CH<sub>2</sub>-OR<sub>8</sub> in the instant claim. Therefore, the instant claim is anticipated by Senn-Bilfinger et al.

**14.** Claim 15 is rejected under 35 U.S.C. 102(b) as being anticipated by Senn-Bilfinger et al., WO 98/42707. Senn-Bilfinger et al. disclosed the instant claimed compound on page 2, lines 2-5, wherein R<sub>5a</sub> being methylenedioxy radical (-O-

CH<sub>2</sub>-O-) which is corresponded to R<sub>5a</sub> being radical –OR' wherein R' is –CH<sub>2</sub>-OR<sub>8</sub> in the instant claim. Therefore, the instant claim is anticipated by Senn-Blifinger et al.

**15.** Claim 15 is rejected under 35 U.S.C. 102(b) as being anticipated by Senn-Blifinger et al., WO 00/26217. Senn-Blifinger et al. disclosed the instant claimed compound on page 2, lines 22-24, wherein R<sub>5a</sub> being 1-4C-alkoxy-1-4C-alkoxy which is corresponded to R<sub>5a</sub> being radical –OR' wherein R' is –CH<sub>2</sub>-OR<sub>8</sub> in the instant claim. Therefore, the instant claim is anticipated by Senn-Blifinger et al.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

**16.** Any inquiry concerning this communication or earlier communications from the examiner should be directed to Niloofar Rahmani whose telephone number is



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571-272-4329. The examiner can normally be reached on Monday through Friday from 8:30 am to 5:00 pm.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thomas Mckenzie, can be reached on 571-272-0670. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

NILOOFAR RAHMANI

06/20 /2006

NR

  
D. MARGARET SEAMAN  
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